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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------|------------------|
| 10/790,617 | 03/01/2004 | RameshBabu Boga | KCX-827 (20129) | 8844 |
| 22827 | 7590 | 11/26/2007 | EXAMINER | |
| DORITY & MANNING, P.A. POST OFFICE BOX 1449 GREENVILLE, SC 29602-1449 | | | DIRAMIO, JACQUELINE A | |
| | | ART UNIT | | PAPER NUMBER |
| | | 1641 | | |
| | | MAIL DATE | DELIVERY MODE | |
| | | 11/26/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|--------------------|--------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/790,617 | BOGA ET AL. |
| | Examiner | Art Unit |
| | Jacqueline DiRamio | 1641 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 September 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 8, 9 and 22-38 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-7 and 10-21 is/are rejected.
- 7) Claim(s) 16 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 18 June 2004 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 7/13/04; 7/16/04; 9/13/04;
10/8/04; 12/16/04; 4/27/05
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1 – 7 and 10 – 21, as well as the species election of alpha-naphtholbenzein, in the reply filed on September 17, 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 8, 9, and 22 – 38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claim Objections

Claim 16 is objected to because of the following informalities:

Claim 16 recites the phrase "detection probes conjugated with a specific binding for the analyte," which appears to be missing the term "member" after "specific binding."

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13, 14, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the term “the analyte,” which lacks antecedent basis.

Claims 14 and 16 recite the term “said … complexes thereof,” which lacks antecedent basis and is vague and indefinite, because it is unclear what the detection probes are forming complexes with.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 – 7 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Harris et al. (US 5,599,913).

Harris et al. teach an optical sensor (assay device) for detecting the presence or absence of amines within a test sample, said optical sensor comprising a fluidic medium that defines a reagent area (detection zone), wherein a chromoionophore (chemichromic dye) is contained within said reagent area, said chromoionophore being capable of undergoing a detectable color change upon reaction with one or more amines (see column 3, lines 26-37; column 4, lines 7-58; column 6, lines 46-66; column 7, lines 1-25; and Example 9).

With respect to Applicant's claims 2 – 7, Harris et al. teach that the chromoionophore can comprise a variety of chemical compounds that read on Applicant's claims 2 – 7 (see column 4, lines 7-58; and column 5, lines 1-67).

With respect to Applicant's claim 10, the fluidic medium can comprise a filter paper test strip (porous membrane) (see Example 9).

Claims 1 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Attar (US 4,840,919).

Attar teaches a gas dosimeter (assay device) for detecting the presence or absence of amines within a test sample, said dosimeter comprising a carrier (fluidic) medium that defines a reagent area (detection zone), wherein a colorimetric reagent (chemichromic dye) is contained within said reagent area, said colorimetric reagent being capable of undergoing a detectable color change upon reaction with one or more amines (see Figures; and column 1, lines 7-22; column 2, lines 26-50; column 3, lines 52-68; column 4, lines 1-59; and column 5, lines 3-10).

With respect to Applicant's claim 10, the carrier medium can comprise a porous membrane (see column 4, lines 44-55).

Claims 1 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Miller et al. (US 7,014,816).

Miller et al. teach an indicator device (assay device) for detecting the presence or absence of amines within a test sample, said device comprising a polymeric matrix

(fluidic medium) that defines an indicator area (detection zone), wherein an indicator compound (chemichromic dye) is contained within said indicator area, said indicator compound being capable of undergoing a detectable color change upon reaction with one or more amines (see Figures; and column 3, lines 39-50; column 4, lines 4-49; column 5, lines 8-34; and column 6, lines 5-25).

With respect to Applicant's claim 10, the polymeric matrix can comprise a porous membrane (see column 3, lines 40-60; and column 5, lines 21-33).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 – 7, 10, 12 – 14 and 16 – 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels et al. (US 2006/0008921) in view of Miller et al. (US 7,014,816) and Harris et al. (US 5,599,913).

Daniels et al. teach an immunochromatographic test strip (assay device) for detecting the presence or absence of an analyte within a test sample, said test strip comprising a porous membrane that is in fluid communication with a detection reagent (probes) conjugated with a specific binding member for the analyte, said porous membrane defining:

a capture region (second detection zone) within which a capture reagent is immobilized to bind to said detection reagent or complexes thereof to generate a detectable (detection) signal, wherein the amount of analyte in the test sample is proportional to the intensity of the detectable signal (see Figures 1 and 3; and paragraphs [0108]-[0120], [0133], [0201]-[0203], and [0232]-[0236]).

Daniels et al. teach the use of their test strip to detect various analytes, including bacteria, viruses and other microorganisms, such as those found in biological fluids, water or food stuffs (see paragraphs [0094], [0095], and [0232]-[0236]). However, Daniels et al. fail to teach the detection of amines, wherein the porous membrane includes a first detection zone that comprises an immobilized chemichromic dye in the form of a triarylmethane dye, said dye capable of undergoing a detectable color change upon reaction with one or more amines.

Miller et al., which was discussed in the 102(e) rejection above, teach a device for detecting amines in a test sample, wherein the device comprises a substrate and a polymeric matrix that contains an indicator compound. The indicator compound can comprise various dyes that are capable of undergoing a detectable color change upon reaction with one or more amines. Amines represent volatile bases that are generated

by food decomposition, therefore, the device provides an effective means to indicate the presence of an unwanted biological agent, such as bacteria or fungi, in a sample, particularly a food sample, by colorimetric detection of amines (see Figures; and column 1, lines 20-61; column 3, lines 39-50; column 4, lines 4-49; column 5, lines 8-34; and column 6, lines 5-25).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device for detecting analytes of Daniels et al. a detection zone that comprises a colorimetric reagent that undergoes a color change in the presence of amines as taught by Miller et al. because Miller et al. teach that a device that comprises an indicator dye that undergoes a color change in the presence of amines provides an effective means to indicate the presence of an unwanted biological agent, such as bacteria or fungi, in a sample, particularly a food sample, by colorimetric detection of amines.

However, Miller et al. fail to teach that the indicator dye specifically comprises triarylmethane, including those recited in Applicant's claims 4-7 and 17-20.

Harris et al., which was discussed in the 102(b) rejection above, teach an optical sensor for detection of amines in a sample, wherein the sensor contains various chromoionophores that are capable of undergoing a detectable color change in the presence of the amines. The chromoionophores comprise various chemical compositions, which include triarylmethanes and the various triarylmethane structures recited in Applicant's claims 4 – 7 and 17 – 20 (see column 3, lines 26-37; column 4, lines 7-58; column 6, lines 46-66; column 7, lines 1-25; and Example 9).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the indicator dye of the device of Daniels et al. and Miller et al. with a triarylmethanes, including those recited in Applicant's claims 4-7 and 17-20, as taught by Harris et al. because Harris et al. teach the benefit of chromoionophores that comprise various chemical compositions, which include triarylmethanes and the various triarylmethane structures recited in Applicant's claims 4 – 7 and 17 – 20, because these compositions are capable of undergoing a detectable color change upon reaction with amines.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels et al. (US 2006/0008921) in view of Miller et al. (US 7,014,816) and Harris et al. (US 5,599,913), as applied above, and further in view of Douglas et al. (US 5,843,691).

The Daniels et al., Miller et al., and Harris et al. references discussed above fail to teach that the porous membrane comprises at least one flow channel.

Douglas et al. teach a reagent test strip for measuring the concentration of analyte in a liquid sample, wherein the test strip comprises a bottom layer, a membrane layer, and a metering means. The metering means comprises a fluid transport channel that allows for distributing and guiding a sample along the strip and membrane layer to a plurality of assay areas. The plurality of assay areas each contain a different reagent that react with the analyte to produce a color change (see Figures; Abstract; and column 3, lines 2-35).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Daniels et al., Miller et al., and Harris et al. a flow channel as taught by Douglas et al. because Douglas et al. teach the benefit of including a fluid transport channel within an assay strip in order to allow for distributing and guiding a sample along the strip and membrane layer to a plurality of assay areas, wherein the plurality of assay areas each contain a different reagent that react with the analyte to produce a color change.

Claims 15 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels et al. (US 2006/0008921) in view of Miller et al. (US 7,014,816) and Harris et al. (US 5,599,913), as applied above, and further in view of Lawrence et al. (US 6,099,801).

Daniels et al. teach the inclusion of a control region downstream from said capture region, however, Daniels et al., as well as Miller et al. and Harris et al., fail to teach that the control zone contains a chemichromic dye.

Lawrence et al. teach a pH and amine test element that is useful in the diagnosis of vaginal infections. The test element contains a test section that is capable of detecting volatile amines in a test sample, wherein the amine test section contains an indicator that undergoes a detectable color change in the presence of a volatile amine. The amine test section also contains a second indicator that functions as a control and undergoes a detectable color change regardless of the presence of volatile amines in the test sample. The inclusion of a control that contains a color-changing indicator in

both the pH and amine test sections of the test element is useful in order to assure that the indicator is not malfunctioning for reasons such as manufacturing error in the device, and that the device has been exposed to sufficient sample to produce a reading if the sample is indeed positive (see Figures; Abstract; column 4, lines 5-25 and lines 64-67; column 5, lines 1-17; column 9, lines 54-57; column 10, lines 20-27; column 11, lines 22-54; and column 12, lines 7-27).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Daniels et al., Miller et al. and Harris et al. a control zone with a color-changing (chemichromic) dye as taught by Lawrence et al. because Lawrence et al. teach the benefit of including a control region with a second color-changing indicator, wherein a test area contains a first color-changing indicator, in order to assure that the indicator is not malfunctioning for reasons such as manufacturing error in the device, and that the device has been exposed to sufficient sample to produce a reading if the sample is indeed positive.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

Art Unit: 1641

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Jackie DiRamio
Patent Examiner
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